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ELI LILLY AND COMPANY

By Paula K Davis

Date May 18, 2004

PATENT APPLICATION
IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants	:	James A. Hoffmann, et al)	
)	
Serial No.	:	09/928,198)	
)	
International)	Group Art Unit:
Filing Date	:	August 10, 2001)	1647
)	
For	:	FSH Formulations)	Examiner:
)	R. Deberry
)	
Docket No.	:	X12383N)	

CERTIFICATION UNDER 37 C.F.R. §1.97 (e)

Commissioner for Patents
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Sir:

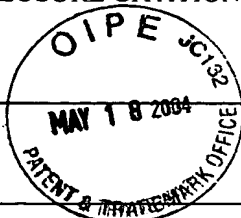
Under the guidelines of 37 C.F.R. §1.97(e), I hereby certify that:
no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application or, to my knowledge after making reasonable inquiry, was known to any individual designated in §1.56(c) more than three months prior to the filing of this statement.

Respectfully submitted,
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May 18, 2004

FORM PTO 1449 (modified) INFORMATION DISCLOSURE CITATION IN AN APPLICATION	Atty. Docket No. X12383N	Serial No 09/928,198
	Applicants James A. Hoffman, et al.	
	Filing Date August 10, 2001	Group 1647



NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. 1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s) publisher, city and/or country where published.	T ⁶
	CCB	AKERS, MICHAEL J. "Excipient – Drug Interactions in Parenteral Formulations." Journal of Pharmaceutical Sciences, Vol. 92, No. 11, November 2002	
	CCC	European Agency for the Evaluation of Medicinal Products, Committee for Proprietary Medicinal Products (CPMP), "Note for Guidance on Maximum Shelf-life for Sterile Products for Human Use After First Opening or Following Reconstitution," Guidance CPMP/QWP/159/96, 1999.	

Examiner Signature	Date Considered
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*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). ² See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

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